

WILMERHALE

August 28, 2014

James C. Burling

By E-mail

+1 617 526 6416 (t)
+1 617 526 5000 (f)
james.burling@wilmerhale.com

The Honorable Mitchell S. Goldberg
United States District Court Judge
United States District Court
for the Eastern District of Pennsylvania
601 Market Street
Philadelphia, PA 19106

Re: *In re Modafinil*, Civ. A. Nos. 06-1797, 06-1833, 06-2768, 08-2141

Dear Judge Goldberg:

I write on behalf of Defendant Cephalon, Inc. ("Cephalon") in response to your e-mail dated August 12, 2014 regarding the above-referenced cases.

1. Sequencing of Motions

Cephalon has no objection to the sequencing of motions proposed by the Court. Some *Daubert* motions, however, are directed at class certification experts, and it may be appropriate to decide those before or at least during any hearings on class certification. In addition, to the extent challenged expert testimony stands in the way of the Court granting any motions for summary judgment, the Court should consider the admissibility of that testimony.

2. Scheduling of FTC Trial

Cephalon submits that it would be inefficient and prejudicial to proceed first with an FTC-only trial followed by a largely duplicative trial of the private plaintiffs' claims. Multiple trials will place undue burdens on the Court, the witnesses (many of whom are former employees), and the parties, all for minimal (or no) efficiency gains. Instead, Cephalon respectfully maintains that all claims against Cephalon should proceed in a single trial. Following that trial, the Court would be well-positioned—aided by post-trial briefing—to decide separately the FTC's equitable claim while disregarding any evidence that would be inadmissible as to that claim. At a minimum, Cephalon suggests the Court consider the appropriate sequencing of trials after summary judgment, *Daubert*, and class certification motions have been decided, as the outcome of those motions may potentially alter the shape of this litigation.

An FTC-only Trial Creates Judicial Inefficiency and Imposes Undue Hardship on Witnesses as well as Cephalon. Holding two separate trials—one FTC trial followed by a private plaintiffs trial—will be duplicative and an inefficient use of the Court's resources, and will require Cephalon to defend the same case twice. Cephalon expects any trial in this case to take over two months to complete. Although the FTC has sued only Cephalon, the substantive testimony and

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exhibits about the settlements and challenged business transactions, as well as the witnesses that will present that testimony, would be substantially identical to the private litigation. The key testimony in these trials will come not from the plaintiffs, but rather from witnesses from Cephalon and the Generic Defendants—many of whom are now ex-employees located across the country, and for whom travel to trial and absence from work will pose significant burdens. In addition to fact testimony, much of the expert testimony would be substantially duplicative if there were separate trials against Cephalon. The FTC and the private plaintiffs have cross-designated many experts, including experts on the value of the Teva intellectual property that was licensed (Hoxie and Ahner), and the medical uses of modafinil (Mignot). Likewise, many of Cephalon's expert witnesses (and their testimony) would be substantially the same in both cases.

Nor are any efficiencies gained by holding the FTC trial first. As this Court has recognized, even if the FTC were to prevail in an earlier trial, there would be no preclusive effect against Cephalon due to the Seventh Amendment. In the Court's August 12 email, Your Honor raises the issue of the differences in the preclusion rulings as to the FTC and the private plaintiffs. To be sure, if the rulings were reversed—if the patent evidence were permitted in the FTC bench trial but not in the jury trial—then a combined trial likely would not be feasible, as the jury could potentially hear evidence it should not. Here, however, the jury is permitted to hear evidence regarding the patent, and to the extent such evidence is irrelevant to the FTC's case, the Court can disregard that evidence in ruling on that claim. As such, there is no prejudice to the FTC.

Moreover, requiring Cephalon to litigate both class certification and the FTC trial at or around the same time, as Your Honor suggested in his August 12, 2014 email, would impose an unfair and unnecessary burden. Class certification is a critical, case-defining issue for both the Direct Purchaser case and the End-Payor case, the Defendants have strong arguments that neither class can be certified, and evidentiary hearings have been requested and are favored under Third Circuit law. *See In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 309 (3d Cir. 2009). Cephalon would be disadvantaged by having to address the critical class issues while at the same time preparing for and litigating the FTC trial, while the class plaintiffs could focus solely on certification and the FTC could focus solely on trial.

The American Express Decision Turned on Inefficiency Concerns and Enforcement Considerations Not Present Here. Your Honor identified *In re American Express Anti-Steering Rules Antitrust Litigation*, 2014 WL 558759 (E.D.N.Y. Feb. 11, 2014), as lending support for an initial, FTC-only trial. Respectfully, the *American Express* case is distinguishable from the present case in important respects. Most significantly, unlike in *American Express*, there is considerable overlap in this litigation between the FTC case and the private plaintiffs' cases, and no material inconsistency. In *American Express*, by contrast, the court reasoned that the two cases "advance[ed] fundamentally different interests," and noted that "the two sets of plaintiffs advance different theories of the relevant market" that the defendants hoped to "exploit" in a joint trial. *Id.* at *2. Importantly, here, there is no liability claim that the FTC is pursuing that

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the private plaintiffs are not pursuing. In short, the Court will not need to “empanel a jury for a months-long consolidated trial only to shuttle the jury in and out of the courtroom depending on the evidence presentation or argument of the day or hour,” as the Court in *American Express* worried. *Id.*

Second, the FTC has no compelling need for an expedited resolution of its case that would offset the inefficiencies and prejudice created by separate trials. In *American Express*, the Government sought to enjoin an ongoing practice it contended caused harm to the public. Here, as the Court has noted, generic entry of modafinil has already occurred.

Finally, unlike *American Express*, this is not a case where the FTC brought suit and then private litigation followed. The private suits here were filed first, nearly two years before the FTC’s. There is certainly no ban on consolidating an FTC action with a private plaintiff action. *Cnty. Publishers, Inc. v. Donrey Corp.*, 892 F. Supp. 1146 (W.D. Ark. 1995). Indeed, the FTC has previously made clear *in this case* that it is “willing to consent to a joint trial on liability ... [i]n the interest of judicial economy.” Letter from Markus H. Meier to the Court (08-2141, Dkt. 205) (July 31, 2013) at 7 (emphasis added). While the FTC may now reverse its position, any claim by the FTC that it *must* try its case separately should ring hollow in light of this prior concession.

Ultimately, as the court in *American Express* itself recognized, the district court enjoys “broad discretion” when deciding whether “to consolidate actions for trial when there are common questions of law or fact to avoid unnecessary costs or delay.” *Johnson v. Celotex Corp.*, 899 F.2d 1281, 128485 (2d Cir. 1990); *see also Am. Express*, 2014 WL 558759 at *2; Fed.R.Civ.P. 42(a). In this litigation, for the reasons discussed above, consolidating trials is the most efficient and least prejudicial course.

Pending and Forthcoming Motions May Significantly Alter the Contours of the FTC’s and Private Plaintiffs’ Cases. Even if the Court were inclined at this juncture to order an early FTC-only trial despite the foregoing, Cephalon submits that it is unnecessary and inadvisable to set final trial configuration at this time because resolution of the remaining summary judgment, *Daubert*, and class certification motions have the potential to impact the parties, claims, and scope of testimony in any trial. Only after such rulings could the Court fully and accurately weigh the benefits of consolidation against any downside. And no efficiency is lost by deferring a decision on trial sequencing until after resolution of these motions because nearly every issue in the *Daubert* motions must be resolved before any FTC trial commences anyway, even in light of the Court’s prior substantive rulings.¹

¹ E.g., Defs.’ Mot. to Exclude the Testimony of Pls.’ Proposed Econ. Experts Hal J. Singer, Raymond S. Hartman, Roger G. Noll, Jeffrey Leitzinger, Keith B. Leffler, and Einer Elhauge (08-2141, Dkt. 277) (April 4, 2014); Defs.’ Joint Mot. to Exclude Damages Opinions of Pls.’ Experts Drs. Hartman, Leffler, Leitzinger, and Noll (08-2141, Dkt. 273) (April 4, 2014); Defs.’ Mot. to Exclude Testimony of Pls.’ Expert Thomas Hoxie (08-2141,

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In addition, Cephalon will shortly be filing another motion that may have a direct impact on the FTC trial—a motion to strike the FTC’s new, previously disclaimed disgorgement remedy.² As Cephalon will demonstrate in the motion to strike, the FTC is precluded from seeking disgorgement as a remedy (i) under its governing statute, (ii) under its own policy statement in effect at the time it filed its complaint, and (iii) because it did not plead a disgorgement remedy and has expressly disavowed seeking such a remedy throughout this case. For example, the FTC previously represented to the Court that: “We’re not seeking damages. We don’t have the authority to do that. We’re not seeking any kind of monetary relief. We’re seeking only an injunction...” Hearing Tr. (06-1797, Dkt. 71) (April 22, 2010) at 61:8-14. The ruling on this motion will significantly impact any trial, including whether evidence is necessary on issues related to disgorgement.

For these reasons, Cephalon respectfully suggests that the Court decline to order an initial, FTC-only trial. At a minimum, Cephalon requests that the Court permit full briefing on the consolidation issue, as in the *American Express* case, before it rules on this important issue.

3. Impact of Prior Rulings on Pending *Daubert* Motions

Although Cephalon respectfully disagrees with the Court’s July 29 ruling on the FTC preclusion motion, it would be consistent with that ruling to grant FTC’s Motion to Exclude Opinions of Cephalon’s Ten Patent Experts (08- 2141, Dkt. 280) (April 4, 2014), *as to the FTC only* and because the FTC has not advanced either a *Walker Process* or sham litigation claim. Although certain private plaintiffs’ groups (e.g., the Direct Purchasers) joined in the FTC’s motion, the motion should be denied as to any private plaintiffs, as patent issues remain part of that case, both as to claims under *Actavis* and as to *Walker Process*/sham litigation claims (to the extent such claims have been properly asserted). Mem. Op. (06-1797, Dkt. 600) (Mar. 13, 2014).

All other *Daubert* issues remain live and contested. As noted above, many of these *Daubert* issues impact the FTC case and must be resolved prior to any trial in that case.

Sincerely,

/s/ James C. Burling

James C. Burling

Dkt. 271); Defs.’ Mot. to Exclude the Testimony of Pls.’ Proposed Expert John R. Thomas (08-2141, Dkt. 276) (April 4, 2014).

² As the Court noted in its July 29 opinion, its ruling that the FTC’s case is not moot did not address the whether the FTC is entitled to the new relief it now seeks. Mem. Op. (08-2141-Dkt. 322) (July 29, 2014), at 2 n.2.



UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, DC 20580

Bureau of Competition
Health Care Division

August 28, 2014

The Honorable Mitchell S. Goldberg
United States District Court
Eastern District of Pennsylvania
601 Market Street
Room 4000
Philadelphia, Pennsylvania 19106-1797

Re: *FTC v. Cephalon, Inc.*, No. 08-cv-2141 (MSG) (E.D. Pa.), and Related Cases

Dear Judge Goldberg:

The Federal Trade Commission respectfully submits this letter in response to your email dated August 12, 2014.

1. Remaining Motions

The FTC agrees with the Court's plan to prioritize the *Actavis*-related motions for summary judgment. Cephalon's motion for summary judgment (08-cv-2141, doc. 275) is the only pending dispositive motion in the FTC's case. If it is denied, the FTC's case will be ready for trial. As described below, the other pending motions in the FTC's case (all *Daubert* challenges) could be decided during the course of a bench trial.

2. Trial Structure

The FTC believes that the trial structure proposed by the Court—setting a date for a bench trial in *FTC v. Cephalon* once the motions for summary judgment are resolved—is the best way to proceed. This approach offers three compelling advantages.

First, it would avoid the significant burden of a cumbersome joint trial. While all of the cases include a reverse-payment claim against Cephalon, the private actions include additional claims, additional parties, and a number of additional issues. Even in a joint trial, those cases would be tried to a different fact-finder evaluating a different evidentiary record. Moreover, much of the evidence presented at a joint trial (in particular, patent-related evidence) would be wholly irrelevant to the FTC's case. The FTC has not alleged a claim of *Walker Process* fraud and this Court has ruled that, in the FTC's case, Cephalon will be precluded from presenting any

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evidence related to the potential validity, enforceability, or infringement of its patent.¹ These differences raise the prospect of having to “shuttle the jury in and out of the courtroom depending on the evidence presentation or argument of the day or hour.” *In re Am. Express Anti-Steering Rules Antitrust Litig.*, Nos. 11-md-02221, 10-cv-04496, 2014 WL 558759, at *2 (E.D.N.Y. Feb. 11, 2014). As in *American Express*, “the mechanics of a consolidated trial would likely outweigh any gains in terms of judicial efficiency.” *Id.*

Scheduling the FTC’s case for a separate trial offers a far more efficient way to resolve the remaining claims and issues in these cases. The FTC’s case involves a single claim against a single defendant. As the Court noted, the FTC’s case can proceed to trial without first resolving any class certification issues. Furthermore, the Court could resolve the remaining *Daubert* motions during the bench trial, by hearing testimony from a challenged expert before deciding whether it met the standards for admissibility. A bench trial would offer the added benefit of familiarizing the Court with the issues, thus putting it in a better position to manage a subsequent jury trial (if one were ultimately necessary).

Second, scheduling the FTC’s case for trial may help facilitate settlement. The act of setting a trial date often prompts serious settlement discussions, and the FTC’s case is the closest to being ready for trial. Furthermore, a decision in the FTC’s case will likely encourage resolution of the remaining cases. If the FTC prevails and the Court orders Cephalon to disgorge its unlawful gains, this money would be placed into a disgorgement fund, which could be used for settlements with the private plaintiffs.² As Cephalon would have already forfeited this money, it would have a strong incentive to see that the fund is used to settle the remaining cases. Additionally, regardless of the outcome, the result in the FTC’s trial would send a signal about the relative strengths of the remaining parties’ positions, which would likely facilitate settlement. In fact, this very scenario occurred in the recent Apple E-Books antitrust litigation. In that case, the court first held a government-only bench trial with a separate trial to follow for the state and consumer plaintiffs. After the government prevailed at its trial, Apple agreed to a \$450 million dollar settlement with the remaining plaintiffs, contingent on the outcome of Apple’s appeal of the prior decision.³

Third, the Court’s proposal to proceed first with a separate trial of the FTC’s case is supported by long-standing precedent recognizing the importance of prompt and efficient resolution of federal government antitrust actions. The Supreme Court has recognized “the unquestionably sound policy of not permitting private antitrust plaintiffs to press their claims against alleged violators in the same suit as the Government.” *Sam Fox Publ’g Co. Inc. v. United States*, 366 U.S. 683,

¹ Mem. Op. (July 29, 2014) (doc. 322).

² The FTC has set up such funds in previous cases where disgorgement was part of the remedy. See *FTC v. Skechers U.S.A., Inc.*, No. 1:12-cv-1214 (May 16, 2012) (consent decree including \$40 million in disgorgement to be placed into a consumer relief fund); *FTC v. Mylan Labs., Inc.*, No. 1:98-cv-3114 (D.D.C. Feb. 9, 2001) (consent decree including \$100 million of disgorgement to be placed into two funds to settle concurrent state lawsuits).

³ See Mem. Op. & Order., *In re Elec. Books Antitrust Litig.*, No. 11-md-2293 (S.D.N.Y. Aug. 1, 2014) (granting preliminary approval for settlement).

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693 (1961).⁴ This principle seeks to avoid “encumbering government antitrust suits with a multitude of collateral issues and of assuring to the government full control of the prosecution and settlement of such public antitrust actions” *Int’l Mort. & Inv. Corp. v. Von Clemm*, 301 F.2d 857, 862 (2d Cir. 1962). Furthermore, Congress has specifically exempted federal government antitrust actions from the statute allowing courts to consolidate multidistrict litigation, 28 U.S.C. § 1407(g). In doing so, it “articulated a strong public policy against combining antitrust complaints brought by the Government with private antitrust damages suits.” *United States v. Dentsply Int’l, Inc.*, 190 F.R.D. 140, 144-45 (D. Del. 1999).⁵ As the *Dentsply* court explained, Congress “has expressed a clear public policy of prioritizing prompt resolution of Government antitrust claims to provide expeditious relief to the public over possible efficiencies to be gained from consolidation with private antitrust damages actions.” 190 F.R.D. at 145.

For these and other reasons, where the government has sought to proceed separately, courts have consistently followed this Court’s proposed approach of proceeding first with a trial of the government’s antitrust claims:

- *In re American Express Anti-Steering Rules Antitrust Litigation*, Nos. 11-md-02221, 10-cv-04496, 2014 WL 558759, at *2 (E.D.N.Y. Feb. 11, 2014).
- *In re Electronic Books Antitrust Litigation*, Nos. 12-cv-3394, 11-md-2293, 2013 WL 1759567, at *2 (S.D.N.Y. Apr. 24, 2013).
- *United States v. Dentsply International, Inc.*, 190 F.R.D. 140, 144-45 (D. Del. 1999).

To our knowledge, no court has ever ordered the U.S. government to try an antitrust enforcement action jointly with private plaintiffs when it did not consent to do so.⁶

⁴ See also *United States v. Visa U.S.A., Inc.*, No. 98-cv-7076, 2000 WL 1174930, at *1 (S.D.N.Y. Aug. 18, 2000) (“While Discover undoubtedly has an interest relating to the subject of the action, in government antitrust actions, courts have uniformly recognized that the government represents the public interest in competition, unless a private party makes an extraordinary showing to the contrary.”); *United States v. Int’l Bus. Machs. Corp.*, 62 F.R.D. 530, 532 n.1 (S.D.N.Y. 1974) (“It is a firmly established general principle that a private party will not be permitted to intervene in government antitrust litigation.”).

⁵ Although *Dentsply* was a U.S. Department of Justice case, it applies with equal force to an FTC action. See *Stephen L. LaFrance Pharmacy, Inc. v. Unimed Pharm., Inc.*, No. 09-cv-1507, 2009 WL 3230206, at *3 (D.N.J. Sept. 30, 2009) (observing that, under 28 U.S.C. 1407(g), the Judicial Panel on Multidistrict Litigation lacks jurisdiction over FTC antitrust cases).

⁶ See *Dentsply*, 190 F.R.D. at 145 n.22 (noting lack of precedent). When the District Court for the District of Columbia granted Cephalon’s motion to transfer the FTC’s case, it expressly noted that it was not consolidating the government’s case with the private actions pending in the Eastern District of Pennsylvania. As the transferring court explained: “In the event that Cephalon moves for consolidation post-transfer pursuant to Fed.R.Civ.P. Rule 42(a)7—which is mere speculation at this juncture—the FTC may argue to that court that consolidation of government and private antitrust actions is inappropriate and contrary to public policy . . .” *FTC v. Cephalon, Inc.*, 551 F. Supp. 2d 21, 32-33 (D.D.C. 2008). Although the cases have proceeded through discovery under a joint coordination order, Cephalon has never invoked the option of moving to consolidate the FTC action for purposes of trial.

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3. Other Motions

Your Honor has asked Cephalon whether it agrees that the FTC's *Daubert* motion to exclude opinions of Cephalon's ten patent experts should be granted, given the Court's July 29, 2014 collateral estoppel decision. As noted above, the Court held that Cephalon is precluded from presenting in the FTC's case "any evidence at trial related to the potential validity, enforceability, or infringement of its RE '516 patent."⁷ In that collateral estoppel decision, the Court explained that Cephalon's inequitable conduct before the patent office "forecloses any attempt to use the strength of its patent, or litigation and business risk, as a defense" to the FTC's reverse-payment claim.⁸ The Court's collateral estoppel decision therefore encompasses the full relief sought by the FTC's *Daubert* motion: precluding Dr. Gerald Dahling from testifying about the RE '516 patent, patent infringement litigation concerning the RE '516 patent, or the reasonableness of the patent settlements challenged in this case in light of the RE '516 patent; and precluding Cephalon's other nine patent experts from testifying at the FTC trial.⁹ We therefore believe the FTC's *Daubert* motion should be granted in full.

The FTC is not aware of any other pending motions implicated by any of the Court's other recent rulings.

Sincerely,



Markus H. Meier
Attorney for Plaintiff Federal Trade Commission

⁷ Mem. Op. at 15 (July 29, 2014) (doc. 322).

⁸ *Id.*

⁹ See Proposed Order (outlining proposed relief) & Memorandum at 4 n.6 (explaining that Dr. Dahling's proposed testimony covers topics beyond the RE '516 patent), Plaintiff Federal Trade Commission's Motion to Exclude Opinions of Cephalon's Ten Patent Experts (08-cv-2141, doc. 280).